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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,833	04/27/2001	James J. Barry	12013/58401	8482

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/842,833

Applicant(s)

BARRY ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 21 November 2002 is: a) ☐ approved b) ☒ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 11, 2003 has been entered.

### ***Drawings***

The objection made to the drawings in the previous Office Action is not met. The proposed drawing correction filed on May 09, 2003 is not approved because the Examiner was unable to find the attachment with the drawings changes.

The Examiner objects the drawings, specifically to figures 1-3, because element 11 looks like a hollow part of element 10. Element 11 should show the same lines (in different direction) as element 10 in order to show that is a solid body. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Correction is required.

### ***Response to Amendment***

Applicant's arguments with respect to the 35 USC 103(a) rejection to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 6, 7 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al US Patent 6,287,285 B1.

Michal et al discloses a coated implant delivery system comprising an implant delivery device (10) with a first end (22), a second end (11), an inner lumen (see Fig. 8) and a stent (30). The first end has a releasable implant retention region (13), the region has an accessible surface (surface of the balloon), the accessible surface has a first implant adhesion-resistant coating (20) (see col. 7, lines 3-6; col. 7, lines 28-48) and the stent has a first implant coating (19) (see col. 10, lines 14-37). The two coatings are in physical communication with the stent and the accessible surface and the first implant coating face the releasable implant retention region.

Stent (30) discloses a coating (18) made of two layers (19 & 20) (see Fig. 12 and col. 12, lines 23-27). The Examiner interpreted layer (20) of the stent (30) as being part of the retention region (13) because the layer (20) is in physical contact with the wall of the balloon (13). The

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Examiner interpreted layer (19) as being part of the stent because is in physical contact with the stent wall.

Regarding claims 6 and 7, see col. 1, lines 15-35 .

Regarding claim 11, see col. 12, lines 14-17.

The claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Sydney et al US Patent 6,306,144 B1.

Michal et al discloses the invention substantially as claimed. Additionally, Michal et al discloses two coaxial sleeves positioned in physical communication with the retention region. The Examiner interpreted the two coating (19 & 20) as being the two coaxial sleeves. The two coatings run along the length of the stent, therefore, the two coatings are coaxial to the axis of the stent and have an open mesh sleeve configuration. However, Michal et al does not disclose an exterior of the second end of the implant delivery device treated with a second adhesion-resistant coating, a second adhesion-resistant coating on the accessible surface and a non-adhesive coating made of hydrogel.

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Sydney et al teaches a stent delivery system having an implant delivery device (10), an elongated member (22), an inflatable member (18) and a stent (17). The elongated member (22) has a first end and a second end. The first end has a first coating and the second member has a second coating (see col. 2, lines 41-56 and col. 3, lines 16-19). The balloon comprises three different areas (32, 30 & 36) coated with two different lubricants (see col. 4, lines 52-62) for the purpose of avoiding unexpected movement of the stent when it is installed within the human body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the type of lubricants of the Michal et al reference with the different lubricants and the different coating location at the catheter of the Sydney et al reference in order to avoid unexpected movements of the stent during the installation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Sahatjian et al US Patent 6,409,716 B1.

Michal et al discloses the invention substantially as claimed. However, Michal et al does not disclose a coating made of carbowax.

Sahatjian et al teaches a delivery system comprising an expandable balloon (4) and a stent (50). Additionally, Sahatjian discloses a coating soluble in water (e.g. carbowax) for the purpose of having a smooth delivery through the blood vessel (col. 3, lines 57-63).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating of the Michal et al reference with the carbowax coating of the Sahatjian et al in order to have a smooth delivery through the blood vessel (col. 3, lines 57-63).

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Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Brown US Patent 6,348,060 B1.

Michal et al discloses the invention substantially as claimed. However, Michal et al does not disclose a coating made of polymethacrylic (PEO).

Brown teaches a delivery system (10) comprising an expandable balloon (14) and a stent (18). Additionally, Brown discloses a coating made of PEO for the purpose of allowing a low profile on deflation of the balloon (see col. 4, lines 20-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating of the Michal et al reference with the PEO coating of the Brown in order to allow a low profile on deflation of the balloon (see col. 4, lines 20-37).

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

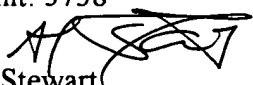
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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Alvin Stewart

July 11, 2003